

REMARKS

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected claims 1, 3-4, 12-16, 22 and 24-25 as being unpatentable pursuant to 35 U.S.C. § 103(a) over U.S. Patent No. 2003/0139762 ("Lee") in view of U.S. Patent No. 5,797,878 ("Bleam").

Applicants have carefully considered the Examiner's comments. In response, Applicants submit the declaration of David G. Burton as evidence of non-obviousness. In light of Mr. Burton's declaration, Applicants respectfully submit that the prior art of record does not disclose all of the limitations of Applicants' claims and Applicants' claims would not be readily apparent from the prior art. Therefore, Applicants respectfully submit that the claims are now in condition for allowance.

As explained by Mr. Burton, Lee relates to a method of making an angioplasty balloon. (Burton Decl. ¶ 3). Lee claims that an advantage of the manufacturing method is that low profile and flexibility are achieved. (¶ [0027], line 9; Burton Decl. ¶ 3). Specifically, Lee's manufacturing method involves inserting an inner tube 106 through a shortened outer tube 102 to form a slug 100, as shown in Figure 2. (¶ [0025]; Burton Decl. ¶ 3). The slug 100 is then placed in a mold and heated and pressurized to form a balloon. (¶ [0025]; Burton Decl. ¶ 3). In the finished balloon, the shortened outer tube 102 forms the working length 44, and the inner tube 106 forms the proximal and distal tapers 48, 50. (¶ [0025], lines 13-17; Burton Decl. ¶ 3). As a result, less tube material is provided to the tapers 48, 50 than to the working length 44. (¶ [0027], lines 1-3; Burton Decl. ¶ 3).

By contrast, the claimed inventions relate to a medical balloon with enlarged radii at the working length-to-taper transition and the taper-to-neck transition. (Burton Decl. ¶ 4). The enlarged radii provide smooth transitions from the working length to the taper and from the taper to the neck. (Burton Decl. ¶ 4). As a result of the smooth transitions, lower forces are required to withdraw the balloon catheter through a delivery sheath or other conduit. (¶ [0044]; Burton Decl. ¶ 4). This advantage solves a number of potential problems. (Burton Decl. ¶ 4). Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to

pull back through a conduit after use. (Burton Decl. ¶ 4). This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]; Burton Decl. ¶ 4). The claimed balloon catheter may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon. (¶ [0044]; Burton Decl. ¶ 4).

As Mr. Burton explains, Lee does not relate to the balloon profile that the Applicants developed. (Burton Decl. ¶ 5). As explained above, Lee's balloon has tapers with a thinner wall thickness than the working length. (Burton Decl. ¶ 5). By contrast, the claimed inventions relate to enlarged radii at the transitions between the working length and the tapers, and the transitions between the tapers and the necks. (Burton Decl. ¶ 5). Not only is Lee related to an entirely different geometry than claimed inventions, but Lee does not even mention the transitions between the tapers and the working length and the necks. (Burton Decl. ¶ 5). Since Lee does not even refer to the relevant transitions, Lee also fails to specify any of the specific radii that Applicants discovered for the transitions. (Burton Decl. ¶ 5).

While Bleam generally recognizes the desirability of minimizing cross and recross forces (col. 2:31-34), Bleam solves this problem in a different way than the claimed inventions do. (Burton Decl. ¶ 6). The solution offered by Bleam is to change the angle α of the taper to make the tapered portions of the balloon more tapered. (Col. 5:53-55; 5:62-6:6; Burton Decl. ¶ 6). Bleam's preferred taper angle α is between 7° and 20°, 9° and 12°, or 10° and 11°. (Col. 6:52-56; Burton Decl. ¶ 6). However, this is not the solution that Applicants developed. (Burton Decl. ¶ 6). Instead, as noted above, the claimed inventions relate to a balloon where the radii at the transitions between the working length and the taper and between the taper and the neck region are enlarged—irrespective of the angle of the taper. (Burton Decl. ¶ 6). Like Lee, Bleam does not even mention the transitions that the claimed inventions relate to. (Burton Decl. ¶ 6). Because Bleam doesn't mention the relevant transitions, Bleam also does not specify any dimensions for the transitions, much less the specific radii that Applicants discovered. (Burton Decl. ¶ 6).

In addition to the fact that the written descriptions of Lee and Bleam do not disclose anything about the transitions between the tapers and the working length and

the necks, the figures of Lee and Blead do not provide a suggestion to achieve the claimed inventions. (Burton Decl. ¶ 7). As noted in the specification of the application, the transitions of an inflated balloon may actually look smooth; however when the balloon is deflated, the differences are significant. (¶ [0047]; Burton Decl. ¶ 7). Indeed, the courts and the Patent Office have repeatedly warned against the use of figures for scaling undefined features. *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) ("The district court erred in not properly applying the principles set forth in our prior precedents that arguments based on drawings not explicitly made to scale in issued patents are unavailing."); MPEP § 2125 ("PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE . . . When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.").

Accordingly, it is respectfully submitted that neither Lee nor Blead disclose all of the limitations of Applicants' claims, and there is no suggestion to modify the prior art to achieve Applicants' claim limitations. Specifically, Lee and Blead do not even mention the transitions between the taper and the working length and the necks that the claimed inventions relate to. Moreover, Lee and Blead fail to disclose the specific radii that have been claimed for the transitions. Therefore, Applicants' claims are allowable and the Examiner may withdraw the rejections of the claims. In addition to the limitations noted above, the prior art of record also fails to disclose the combination of additional limitations of Applicants' remaining dependent claims. Because each of Applicants' dependent claims incorporate all of the limitations of allowable independent claims, Applicants' dependent claims are also allowable. Therefore, any further arguments that could be made at this time in support of the additional limitations of Applicants' dependent claims would be superfluous and is unnecessary. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983).

Conclusion

In response to the Examiner's comments, Applicants have submitted the declaration of David G. Burton. As explained by Mr. Burton, neither Lee nor Blean disclose any details about the transitions between the taper and the working length and the necks that the claimed inventions relate to. Therefore, the prior art of record fails to disclose or suggest all of the limitations required by the claims. Thus, Applicants' claims are allowable. Accordingly, Applicants request reconsideration and allowance of the application.

Respectfully submitted,

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